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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/464,426	12/16/99	STALGIS	[illegible]

HM12/0814

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EXAMINER	
FOLEY,S	
ART UNIT	**PAPER NUMBER**
1648	5

DATE MAILED: 08/14/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/464,426	Applicant(s) STALGIS ET AL.	
	Examiner Shanon A. Foley	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 June 2001* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Double Patenting

Claims 10-37 of this application conflict with claims 1-4, 8, 9 of Application No. 09/311,487. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822. The claims in both application are drawn to administering the same amount of ribavirin and pegylated interferon for the same amount of time to eradicate HCV-RNA 24 weeks after the treatment.

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 10-37 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-4, 8, and 9 of copending Application No. 09/311,487. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claims 1-9 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 10-14, 18-24, 26, 27, 44-

46, 50, 54, 58, and 59 of copending Application No. 09/311,487. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in both applications are drawn to a treatment regiment lasting a total of 48 weeks. The treatment regiment in claims 1-9 of the instant application is not limited to any time period. Application '487 is limited in scope to 48 weeks. Each component and the amount of each component administered in both applications is the same and both claim to result in eradication of HCV-RNA for at least 24 weeks after the respective treatment periods. Therefore, narrowing the time frame for administering a treatment for 48 continuous weeks would be an obvious choice by one skilled in the medical arts when confronted with an open-ended time period for administration, as in the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-37 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5, 9-15, 19-25, 29-35, 40-45, 49-55, 59-65, 69, and 70 of copending Application No. 09/650,841. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 1 of the instant application states that therapy is administered in two dose regiments, but there is no detectable break in between the first and the second regiments, and no time period specified for either regiment. Furthermore, the amount of ribavirin and pegylated interferon administered is the same. The administration period in the instant application could be any specific length of time, including those claimed in '841, as long as there is no detectable HCV-RNA for at least 24 weeks after the end of the second treatment period. Therefore, specific

treatment regiments in '841 are obvious modifications to the broader treatment regiment in the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-37 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-43 of U.S. Patent No. 09/464,425. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the instant application are drawn treating hepatitis C patients with ribavirin and interferon alpha derivatives for the same treatment regiments. Substituting non-pegylated interferon alpha for treatment and the instant application would be an obvious choice for one of skill in the art.

Applicant disagrees with this rejection and asserts that the rejection is premature.

Since neither the Office or the MPEP state that piecemeal prosecution is proper, every statute and rule that is appropriate and proper is applied in a first action on the merits.

Claims 1-37 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 and 8-10 of U.S. Patent No. 6,172,046. Although the conflicting claims are not identical, they are not patentably distinct from each other because the only difference between the claimed application and the claims in the patent is the length of time the treatment is carried out. Specific treatment regiments in '046 patent are obvious modifications to the open-ended treatment regiment in the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chemello et al. (Chemello et al. Journal of Hepatology 1994; 21. (Suppl. 1), page S12. Abstract No. GS 5/29), Grint et al. (EP 0 707 855 A2), and Gilbert et al. (WO 95/13090) for reasons of record.

Applicant argues that Chemello et al. do not teach administering pegylated alfa interferon or increasing the dose to decrease viral load. Applicant asserts that Grint et al. teach doses below the effective amount claimed by applicants and does not suggest a motivation to increase the amount. Glibert et al. teach no more than an invitation to experiment with higher dosages. Applicant also states that there is no motivation to combine the references.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The test of obviousness is not an express suggestion of the claimed invention in any or all references but what references taken together would suggest to those of ordinary skill in the art presumed to be familiar with them.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching,

suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

One of ordinary skill in the art at the time the invention was made would have been motivated to extend treatment duration and beyond 24 weeks for HCV-1 patients to increase the rate of success of the combination treatment taught by Chemello et al. and to alleviate side effects by administering lower doses for a longer period of time taught by Grint et al. The values taught by Grint et al. are at the lower end of the range specified in the claims and therefore meet the specific limitations in the claims. Since the lower value in the dose range is met by the reference, the references do not have to teach or suggest the dosage at the higher end of the range. Grint et al does not teach the pegylated forms of interferon alpha. However, Gilbert et al. do. One of ordinary skill in the art at the time the invention was made would have been further motivated to select and evaluate the pegylated interferon alfa-2a or –2b of Gilbert et al. for use in the protocol of Chemello et al. and Grint et al. because the pegylated forms taught by Gilbert et al. are longer acting in vivo and are suitable for treating HCV. From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention because a longer duration of treatment can be accomplished with pegylated forms with fewer side effects. Therefore, the invention as a whole is prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon A. Foley whose telephone number is (703) 308-3983. The examiner can normally be reached on 7:30-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisors, Laurie Scheiner and James Housel can be reached at (703) 308-1122 and (703) 308-4027, respectively. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4426 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SAF
Shanon Foley/SAF
August 7, 2001

LAURIE SCHEINER
PRIMARY EXAMINER